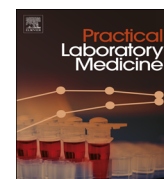


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Comparison of patient hospital length of stay pre and post implementation of the CLINITEK AUWi System from Siemens to screen out negative urine samples intended for culture: A retrospective cohort study

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ABSTRACT

Objective: To determine the impact of using the CLINITEK AUWi System to screen out negative urine samples intended for culture on patient length of stay and culture results at a community teaching hospital.

Design and methods: We used a retrospective cohort design to compare length of stay for patients admitted before and after implementation of the CLINITEK AUWi System to screen urine samples prior to culture. Before implementation, all urine samples were sent to an external laboratory for culture. After implementation, urine samples were screened first, and culture was only performed for those samples above the 325 bacteria/μl cutoff. We assessed patient length of stay before and after implementation.

Results: Our study included 306 samples (168 pre, 138 post). In the post-implementation group, 60.9% of cultures were screened negative and not sent for culture, resulting in fewer negative culture results (74.4% vs 40.7%, $p < 0.001$). Median overall length of stay was reduced from 176 h (IQR 234.75) to 128.5 h (IQR 192.5, $p = 0.018$), a decrease of over 40 h. Differences in length of stay were especially pronounced among female patients, patients aged 80 or over, and patients with urinary tract disorder in the diagnostic differential.

Conclusions: Use of the CLINITEK AUWi System reduced the need for culture by screening out 60.9% of samples as negative, and was associated with a shorter mean length of stay. Our findings have implications for cost savings, due to both the reduced length of stay and the reduced need for culture.

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1. Introduction

Patients with suspected urinary tract infections (UTIs) make up approximately one million hospital admissions per year [1], accounting for up to 40% of healthcare associated infections [2] and causing an estimated 13,000 attributable deaths

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from hospital acquired UTI [3] with over 560,000 hospital acquired UTIs occurring annually in the United States [3]. Because urine culture is the current gold standard of diagnosis [4], patients with suspected infection often remain in the hospital until pending results of the culture are returned, typically 48–72 h later. Often, patients are mistreated or over-treated with empiric therapy in the interim due to the absence of rapid diagnosis. This can potentially lead to unnecessary antibiotic administration and increased bacterial resistance [5].

There are also serious financial considerations related to UTI. The estimated annual cost of community-acquired UTI alone is approximately \$1.6 billion [6] and it has been demonstrated that the empirical cost of treatment increases with bacterial resistance to antibiotics [7]. Due to the very high volume of urine samples processed by laboratories, there is a strong incentive to reduce the costs associated with urine specimens. For example, one laboratory that made efforts to reduce the number of contaminated urine specimens cultured was able to save \$35,250 in laboratory fees in one year [8].

In order to reduce number of cultures and improve turnaround time, several technologies have been developed to screen urine and ascertain negative results, thus preventing unnecessary costs, labor, and time associated with obtaining urine cultures. These technologies include manual and automated urine sediment analyses, urine dipstick testing, and use of clinical diagnostic algorithms to pre-screen patients. Unfortunately, these technologies lack sensitivity [9–11], and the diagnosis of UTI by clinical criteria alone has an error rate of approximately 33% according to a 2010 systematic review of published literature related to diagnosing urinary tract infection [4].

Multiple studies support the use of automated analyses to hasten and improve diagnosis. The CLINITEK AUWi System [12] is one of the lab instruments that can analyze urine for bacteria and other indicators of infection, thus it can be used as a pre-screen for urine culture. This instrument is an automated fluid particle analyzer that uses flow cytometry to quantify formed elements in urine. Previous studies of the CLINITEK AUWi System have found that depending on the lab cutoff values, the device yielded a sensitivity of 81.1% [13] to 97% [14], a specificity of 79% [14] to 83.2% [13], and a false negative rate of 0–10% [13].

Given the demonstrated effectiveness of the CLINITEK AUWi System at screening out negative urine samples from culture, we hypothesized that the faster turnaround available with the CLINITEK AUWi System would have an impact on hospital length of stay for inpatients. This study examines length of stay at our community teaching hospital before and after the implementation of the CLINITEK AUWi System for urine culture screening.

2. Material and methods

2.1. Study population

This study was performed at NYU Lutheran Medical Center, a full service, 450-bed community teaching hospital located in Sunset Park, Brooklyn, NY. Across its many platforms of service, NYU Lutheran treated 179,034 patients in 2014 [15].

2.2. Study design

This study used a quasi-experimental, retrospective cohort design to assess the impact of the availability of urine screening using the CLINITEK AUWi System on hospital length of stay. The CLINITEK AUWi System began to be used in our facility on December 2, 2014, and from that point on, was used to screen all urine samples to determine whether there was a need for culture.

We included electronic medical record charts of admitted patients in our review if they were within one month before and one month after the initiation of the CLINITEK AUWi System (11/1/2014–1/1/2015) and had a urine sample sent to the lab for culture. These patients included any person admitted and excluded those who signed out against medical advice or who expired during the hospital stay. Samples were collected in sterile containers during routine patient care. We identified 5110 eligible samples, from which we randomly selected 306 for chart review.

Before the implementation of the CLINITEK AUWi System, all urine samples processed by the lab at NYU Lutheran were sent to an external laboratory for culture without any prior screening. The culture result was reported to the lab at NYU Lutheran typically 48–72 h later. The lab would then report the result to the physician by updating the patient chart in the electronic medical record.

After implementation of the CLINITEK AUWi System, urine samples for culture were first screened using the CLINITEK AUWi System with a cutoff of 325 bacteria/ μ l, chosen as the highest value that did not cause an unacceptable number of false positives. Similar cutoffs have been chosen by other laboratories [16,17]. The cutoff was determined by the lab prior to implementation in clinical use after testing numerous urine samples from patients suspected of infection against urine culture performed at an external laboratory. With this cutoff in place, all samples that were screened negative for culture by the instrument also had a negative result by culture except for one sample out of eighty that had screened positive by the instrument but had resulted in a negative culture. The instrument was validated according to both the College of American Pathologists performance specifications and those of the New York Department of Health. Having done this, the urine culture screen was implemented as the new protocol for processing all urine specimens. All physicians were notified of the changes in testing protocol before implementation.

After implementation, if the bacterial count was above the 325 bacteria/ μ l cutoff, it was reported to the physician as

bacteria positive with an interpretive comment as follows: “Presumptive positive result for bacteria based on established and validated screening algorithms and protocols using flow cytometric analysis. Specimen has been sent for culture and sensitivity. Final results to follow.” If the bacterial count was below the cutoff, the urine culture screen was reported as bacteria negative with an interpretive comment as follows: “Presumptive negative result for bacteria based on established and validated screening algorithms and protocols using flow cytometric analysis. Culture not performed. Clinical correlation warranted.” Urine culture screen result is electronically reported within thirty minutes. For urine samples that screened positive and were sent to an external laboratory for culture, the process was the same as before from that point forward—results were received by the lab 48–72 h later and entered in the electronic medical record. Urine culture was deemed negative by the external lab if the sample produced no growth or growth lower than 10,000 CFU/ml.

Clinical data collected from the electronic record included comorbidities associated with increased risk of urinary tract disorders such as use of urinary catheterization during inpatient stay, diabetes mellitus, and immunocompromised status [18]. Additional data collected included length of hospital stay and results of urine culture screen and culture. This study was approved by the Lutheran Medical Center IRB.

2.3. Data analysis

We used the Fisher's exact test and the Mann-Whitney *U* test as appropriate to assess differences between the pre-implementation and post-implementation groups on demographic variables, comorbidities, and outcomes of interest. Because the distribution of the continuous data was skewed, median and interquartile range (IQR) were used as measures of central tendency. Stratified analyses were performed by age, sex, and comorbidities to determine how length of stay may be differentially impacted in these groups. Statistical analyses were performed using IBM SPSS Statistics version 22.

3. Results

3.1. Demographics

A total of 306 samples were included in the study; 168 were in the pre group and 138 in the post group. The median patient age in the sample was 74 (IQR 28). Nearly half of patients (47.4%) had a urinary tract disorder in the diagnostic differential, and more than one third (37.9%) had a Foley catheter placed during their stay. Just under one third (30.4%) had diabetes mellitus. Differences between pre- and post-implementation groups were not statistically significant except for urinary tract structural anomalies (9.5% at pre, 2.9% at post; $p=0.021$). Additionally, differences in chronic kidney disease were marginally significant (19.0% at pre, 10.9% at post, $p=0.056$). (Table 1).

P-values in this table are from the Fisher's exact test, except for Age, which is from the Mann-Whitney *U* test.

3.2. Efficacy of the CLINITEK AUWi System in screening out negative samples for culture

Of the pre-implementation group, 125 of the 168 samples (74%) sent for culture were reported by the external lab to be negative (Table 2) with 18 samples reported as contaminated (counted as negative).

After implementation of the CLINITEK AUWi System to screen urine samples there was a reduced need for culture in

Table 1
Demographic data and comorbidities in groups pre- and post-implementation of the CLINITEK AUWi System for urine screening.

	Pre n = 168		Post n = 138		Total		P-value
	n	%	n	%	n	%	
Sex							0.560
Female	96	57.1	84	60.9	180	58.8	
Male	72	42.9	54	39.1	126	41.2	
Urinary tract disorder in diagnostic differential	83	49.4	62	44.9	145	47.4	0.490
Foley catheter placed during stay	69	41.1	47	34.1	116	37.9	0.237
Diabetes mellitus	48	28.6	45	32.6	93	30.4	0.456
Urolithiasis	5	3.0	4	2.9	9	2.9	1
Neurogenic bladder	3	1.8	0	0	3	1.0	0.255
Immunocompromised	3	1.8	1	0.7	4	1.3	0.630
Sickle cell anemia	1	0.6	1	0.7	2	0.7	1
Urinary tract structural abnormalities	16	9.5	4	2.9	20	6.5	0.021
Chronic kidney disease	32	19.0	15	10.9	47	15.4	0.056
Age	Median	IQR	Median	IQR	Median	IQR	0.526
	73.0	28.25	74.5	28.0	74.0	28.0	

Table 2

Urine screen and culture results pre- and post-implementation of the CLINITEK AUWi System.

	Pre n=168		Post n=138		P-value
	n	%	n	%	
Sent for urine culture screen	–	–	138	100	
Positive result	–	–	53	38.4	
Negative result	–	–	84	60.9	
Screen not completed	–	–	1	0.7	
Urine culture completed (of those sent for culture)	168	100	54*	100	
Positive result	43	25.6	32	59.3	< 0.001
Negative result	125	74.4	22	40.7	
Contaminated (counted within negative)	18	14.4	7	31.8	

* This number represents 53 urine samples that were screened prior plus one sample that was not screened prior to culture – this is typically due to a bloody urine sample that cannot be screened.

Table 3

Hospital length of stay pre- and post-implementation of the CLINITEK AUWi System, overall and stratified by group.

	Pre			Post			P-value
	n	Median	IQR	n	Median	IQR	
Overall	168	176.0	234.75	138	128.5	192.5	0.018
Sex							
Female	96	228.5	269.5	84	138.0	211.75	0.002
Male	72	126.0	189.75	54	124.5	166.5	0.949
Age Group							
< 60	52	154.0	241.0	38	102.0	155.0	0.083
60–79	61	168.0	207.5	52	164.5	216.25	0.572
80+	55	211.0	318.0	48	123.0	184.5	0.049
Urinary tract disorder in diagnostic differential							
Yes	83	204.0	218.0	62	135.0	148.0	0.019
No	85	168.0	220.0	76	117.5	240.5	0.323
Foley catheter placed during stay							
Yes	69	256.0	259.5	47	227.0	252.0	0.394
No	99	125.0	170.0	91	93.0	123.0	0.046

60.9% of specimens due to 84 samples screening negative that were subsequently not sent for culture. Of the 54 that were sent for culture, 59.3% were found to be true positives. (Table 2). Of those that were cultured, 7 were reported by the external lab as contaminated and were counted as negative.

3.3. Effect of CLINITEK AUWi System on hospital length of stay

The median length of stay in the pre-implementation group was 176 h (IQR 234.75), and was 128.5 h (IQR 192.5) in the post-implementation group, reflecting a decrease in median length of stay of over 40 h ($p=0.018$). (Table 3).

When stratified by sex, the effect of the CLINITEK AUWi System implementation was more pronounced in the female group, while no significant effect was seen among males (Fig. 1). Among females, the median length of stay dropped from 228.5 (IQR 269.5) at pre to 138.0 (IQR 211.75) at post, a difference of over 90 h ($p=0.049$). (Table 3). It should be noted that male and female patients did not differ significantly in most other factors including age, urolithiasis, diabetes mellitus, and Foley catheter placement, although females were more likely to have had urinary tract disorder in the diagnostic differential (55.0% vs 36.5%, $p=.002$, data not shown).

When the sample was limited to patients with urinary tract disorder listed in the diagnostic differential, we found a decrease in median length of stay of 76 h for male patients (not significant due to small sample size in this category) and

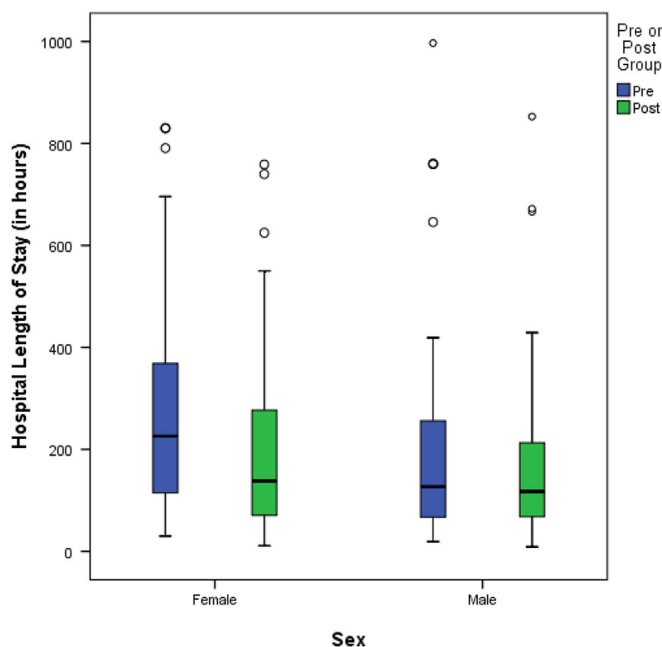


Fig. 1. Boxplots demonstrating reduction in length of stay for female patients.

Note: Two outlier observations of length of stay greater than 1000 h were removed from the plot to improve readability.

70 h for female patients ($p=.055$, data not shown).

In addition, a large decrease in length of stay (88 h) was found among patients who were 80 and over ($p=.022$), although no pattern of association with increased difference in length of stay and increasing age was found (Table 3).

4. Conclusion

Our study found a substantially reduced length of stay in the post-implementation group, and the difference in length of stay was especially pronounced for female patients, patients with urinary tract disorder in the diagnostic differential, and patients over the age of 80.

Given the high prevalence of UTI—nearly half of all US women will suffer from at least one in their lifetime [6]—and that the risk of UTI increases in both sexes with increasing age [19], there are clear benefits to both patients and providers in streamlining the process for urine culture, as it is such a common problem for a large proportion of the population.

Our study's results, in which the instrument was able to screen out 60.9% of specimens to avoid culture, are similar to those in a 2010 study from China, where they found it was possible to forgo 54.9% of cultures using screening [13]. Because culture is the current gold standard of infection diagnosis, the length of time that healthcare providers are forced to wait for an answer often leads to treating the patient empirically without waiting for confirmation [5]. This potential for provider diagnostic error could explain the increased length of stay in the pre-implementation group as patients could have been misdiagnosed as to the source of their infection and possibly treated with unnecessary antibiotics. In our population, only 25.6% of the urine cultures were positive in the pre-implementation group, whereas 59.3% of cultures were positive in the post-implementation group, although the percentage of patients who had a urinary tract disorder listed in their diagnostic differential were similar. The increase in positive cultures in the post group reflects the increased likelihood of obtaining a positive culture due to the decrease in total number of cultures performed. It is possible that the health care providers treating patients in the post-implementation group were able to change their management based on the faster report of the urine culture screen provided to them instead of waiting for culture results as confirmation of the suspected diagnosis. Reducing length of stay for inpatients has been demonstrated in previous studies to improve patient outcome and reduce nosocomial infections [20,21].

Our findings of differences in reduction in length of stay among males as compared with females can most likely be attributed to the higher incidence of UTI among females as compared with males. In a 2011 study that examined the relationship between acquiring a urinary tract infection while inpatient and hospital length of stay, it was found that patients stayed substantially longer with this comorbid complication with a mean of 8.9–11 days [22]. Knowing that women are more likely than men to suffer from a UTI [23], as was reflected in our study, early exclusion or confirmation of this comorbidity would likely explain the relationship we observed between shorter length of stays for women in the post implementation group. This hypothesis is further supported by the fact that a decrease in length of stay was found in both

males and females when the analysis was limited to those with UTI in the diagnostic differential.

Our results have important implications for cost savings and the reduction of unnecessary testing. NYU Lutheran processes between 4000–5000 urine samples per month. It has become common practice for health care providers to routinely order a urine culture in addition to ordering a urinalysis, resulting in increased number, and therefore costs of culturing. A retrospective review conducted by Mayo Clinic assessing adherence to evidence based guidelines for the diagnosis and management of uncomplicated urinary tract infection found that providers ordered urine cultures more frequently than necessary [24]. After having implemented the CLINITEK AUWi System to screen out negative samples, we were able to reduce the need for culture by nearly two thirds. Not only is this reducing unnecessary test performance, this has resulted in saving thousands of dollars for the lab every month as each urine culture costs \$14.00. In addition, when considering that the average cost of inpatient hospitalization in New York State is \$2,2040.00 per day [25], the financial impact of reducing hospital length of stay by using this advanced technology is enormous. Other methods of reducing unnecessary test performance, such as campaigns to further educate providers in discriminating the clinical appropriateness of ordering a urine culture or not have been successful [26,27].

A strength of this study is our data collection of over three hundred patient charts selected at random, which allowed us to gather a diverse patient population within the context of our community teaching hospital.

Our study's main limitation is that the design does not allow us to rule out the possibility that the finding of decreased length of stay could potentially be explained by other, unmeasured factors. However, all patients enrolled in our study were admitted to the hospital within a two-month time frame, and our results demonstrated that the patient groups were similar in terms of most of the variables we measured.

It should also be noted that of the 53 samples that the CLINITEK AUWi System screened positive, only 32 were found to be culture positive. This discrepancy could be due, in part, to antibiotic administration before urine samples were obtained from the patient, since 15 of the 53 samples resulted in no growth upon attempted culture. The CLINITEK AUWi System does not have the ability to screen viable from non-viable bacteria, generating only a quantitative report using flow cytometry. Prior antibiotic exposure cannot be reliably measured in this population, due to the ubiquitous use of antibiotics for urinary tract infection symptoms in the outpatient setting as well as the inpatient use of broad spectrums intended to cover unknown sources of infection.

4.1. Implications

Using the CLINITEK AUWi System as a culture screen in hospital laboratories and outpatient settings to analyze urine may facilitate faster and more accurate diagnosis by the treating physician. If used in the setting of inpatient treatment, reducing length of stay is valuable for both patient and hospital. With improved diagnosis, use of excess antibiotic treatment and subsequent nosocomial infections could be avoided. Many studies have been conducted to identify methods of improving accuracy of diagnosis regarding various urinary infection differentials and evaluation of strategies to reduce antimicrobial therapy [26,28,29]. One study assessed the effects of giving providers behavioral theory-guided audit/feedback regarding UTI management and found improved antibiotic stewardship and increased diagnostic accuracy [26].

On the basis of our findings and in correlation with prior studies showing improved patient outcome due to process improvements [26,27], it may be wise for providers who have access to this technology to wait for the result of screening before starting empirical antibiotic treatment in conjunction with increased differential diagnosis education efforts.

Future research replicating this study using a patient population with no prior antibiotic exposure prior to urine collection and analyses would likely yield even more promising results. Further research could also build on this study to compare admission rates before and after implementation of the CLINITEK AUWi System, as well as to better understand the implications for cost savings and antibiotic stewardship.

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